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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,017	04/17/2001	Elisabeth Lacy Belden	P-9312	6994
27581	7590	03/21/2005	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			RAGONESE, ANDREA M	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/836,017	BELDEN ET AL.	
	Examiner	Art Unit	
	Andrea M. Ragonese	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 January 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 39-79 is/are pending in the application.
- 4a) Of the above claim(s) 46-49, 51 and 54-79 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 39-45, 50, 52 and 53 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed on January 4, 2005 has been entered. Examiner acknowledges that **claim 39** has been amended. Subsequently, **claims 39-45, 50 and 52-53** are under consideration, while **claims 46-49, 51 and 54-79** have been withdrawn from further consideration.

Response to Arguments

2. Applicant's arguments filed January 4, 2005 have been fully considered but they are not persuasive.

In response to applicant's argument that "nowhere in Cragg is there any such discussion [that Cragg discloses an electrode assembly delivery system]" and "Nowhere does Cragg disclose such a system [as one for deploying a lead in a cardiac chamber of a patient]", recitations of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In this case, the prior art of record (Cragg) is *fully capable* of "placing an electrical lead having an electrode assembly in a patient," being "adapted to temporarily couple the electrode assembly to the delivery device" and being "adapted to dislodge the electrode

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assembly" (column 7, lines 20-30). In this passage, Cragg states, "The same method and system can be employed to anchor...electrical leads and any catheters inserted into other body lumens or cavities through a variety of body passageways..." In order to anchor these devices, first the devices must be steered to the location and then delivered to the location for anchoring in the body. The prior art of record discloses an apparatus with the sturcture that is fully capable of carrying out the intended use of the instant invention.

Additionally, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an electrode assembly) are not positively recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Therefore, the rejection of **claims 39-45, 50 and 53** under 35 U.S.C. 102(e) and the rejection of **claim 52** under 35 U.S.C. 103(a) are recapitulated hereinafter.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. **Claims 39-45, 50 and 53** are rejected under 35 U.S.C. 102(e) as being anticipated by Cragg (US 6,315,789).

Regarding **claim 39**, Cragg discloses a system fully capable of placing an electrical lead having an electrode assembly in a patient (column 7, lines 20-30) comprising:

- a. an elongate delivery device (such as 18/70, 72 and associated components) including a proximal portion, an atraumatic distal portion (32) and an electrode retention member (via 22, 34, etc.) fully capable of being adapted to temporarily couple the electrode assembly to the delivery device (columns 14-17), as seen in Figures 6-8; the proximal portion (30) extending proximal to the electrode retention member (such as 22, 34) and the atraumatic distal portion (32) extending distal to the electrode retention member; and
- b. an elongate introducer (such as 18) including a lumen having a diameter sufficient to receive the proximal portion of the delivery device (such as 70, 72) and further including a distal tip fully capable of being adapted to dislodge the electrode assembly

Regarding **claim 40**, Cragg discloses that as applied to **claim 39** as well as a delivery device that is steerable. Applicant has not recited structure that would establish steerability that would define over that disclosed by Cragg.

Regarding **claim 41**, Cragg discloses that as applied to **claim 39** as well as a delivery device that includes a deflection wire (54) coupled to a distal end of the atraumatic distal portion and extending to a proximal end of the delivery device.

Regarding **claim 42**, Cragg discloses that as applied to **claim 39** as well as an atraumatic distal portion is that is shapeable. The scope of this claim is broad and it has not been established when in the manufacturing process that the device is shapeable. The claim does not require the tip to be bendable during use. Thus, the device of Cragg is shapeable and is fully capable of being shaped.

Regarding **claim 43**, Cragg discloses that as applied to **claim 39** as well as an electrode retention member (22, 34) that has an outer surface adapted to form a press fit with an inner surface of a tubular portion of the electrode assembly to temporarily couple the electrode assembly to the delivery device, as recited throughout the specification.

Regarding **claim 44**, Cragg discloses that as applied to **claim 39** as well as an electrode retention member that is a polymeric plug (column 10, lines 40-60). Cragg discloses the use of polymers, and it can be broadly and reasonably interpreted to be a "plug."

Regarding **claim 45**, Cragg discloses that as applied to **claim 39** as well as an electrode retention member that is fully capable of rotation when mounted upon the delivery system.

Regarding **claim 50**, Cragg discloses that as applied to **claim 39** as well as an electrode assembly that would necessarily include an elongate lead extending proximally therefore and a diameter of the introducer lumen that is sufficient to slidably engage the lead (column 7).

Regarding **claim 53**, Cragg discloses that as applied to **claim 39** as well as a distal tip of the introducer that is radiopaque (column 10, lines 40-60).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claim 52** is rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg (US 6,315,789). Cragg discloses a system as recited in **claim 52**, but does not explicitly recited a distal tip of the introducer that includes a nesting taper to aid in alignment of the electrode assembly for dislodging the electrode assembly. However, the tip of Cragg can be considered an equivalent since the function of dislodging the electrode is equally performed. Therefore, it would have been obvious, if not inherent, to substitute one type of tip for another.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is

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not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese whose telephone number is 571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR
March 14, 2005

Henry Bennett
Supervisory Patent Examiner
Group 3700